

FORM PTO-1449 US Department of Commerce Patent and Trademark Office	ATTY DOCKET NO.:	SERIAL NO.:
	DDI-0028-CON1	Unassigned
	APPLICANT: Galen et al.	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	FILING DATE:	GROUP ART UNIT:
	Herewith	Not assigned

## U.S. PATENT DOCUMENTS

EXAM. INITIALS	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
XG	3552929	1/5/71	Fields et al.	23	253	
	3802842	4/9/74	Lange et al.	23	253	
	3809605	5/7/74	Schmitt et al.	162	158	
	3897214	7/29/75	Lange et al.	23	253	
	3973849	8/10/76	Jackson et al.	356	97	
	4050898	9/27/77	Goffe, deceased et al.	23	253	
	4042335	8/16/77	Clement	23	253	
	4223995	9/23/80	Fletcher	356	418	
	4269605	5/26/81	Dean et al.			
	4397956	8/9/83	Maggio	436	34	
	4478744	10/23/84	Mezei et al.			
	4482251	11/13/84	Saylor	356	418	
	4545382	10/8/85	Higgins et al.	128	635	
	4642295	2/10/87	Baker	436	87	
	4645742	2/24/87	Baker	436	15	
	4681444	7/21/87	Ferber et al.	356	318	
	4729657	3/8/88	Cooper et al.	356	319	
	4744657	5/17/88	Aralis et al.	356	319	
	4806468	2/21/89	Wagner et al.	435	7	
	4852025	7/25/89	Herpchohm	364	551.01	

EXAMINER <i>Heber Hale</i>	DATE CONSIDERED <i>Considered</i> <i>in 09/477,900</i> <i>11/15/02</i>
----------------------------	---

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<b>FORM PTO-1449 US Department of Commerce Patent and Trademark Office</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>	<b>ATTY DOCKET NO.:</b> DDI-0028-CON1	<b>SERIAL NO.:</b> Unassigned
	<b>APPLICANT:</b> Galen et al.	
	<b>FILING DATE:</b> Herewith	<b>GROUP ART UNIT:</b> Not assigned

4866644	9/12/89	Schenk et al.	364	571.02	
4935346	6/19/90	Phillips et al.	435	14	
4956301	9/11/90	Ismail et al.	436	87	
4999582	3/12/91	Parks et al.			
5002893	3/26/91	Rosenthal	436	87	
5049487	9/17/91	Phillips et al.	435	4	
5059394	10/22/91	Phillips et al.	422	68.1	
5075077	12/24/91	Durley III et al.	436	170X	
5110745	5/5/92	Kricka et al.			
5169787	12/8/92	Knappe et al.	436	169	
5179005	1/12/93	Phillips et al.	435	14	
5183739	2/2/93	Cohen	435	7.23	
5206144	4/27/93	Zeuthen et al.	435	7.25	
5215716	6/1/93	Arai			
5223219	6/29/93	Subramanian et al.	422	55	
5243516	9/7/93	White			
5258163	11/2/98	Krause et al.	422	58	
5271895	12/21/93	McCroskey et al.	422	58	
5281395	1/25/94	Markart et al.	422	82.05	
5284777	2/8/94	Rosenthal et al.	436	518	
5304468	4/19/94	Phillips et al.			
5366868	11/22/94	Sakamoto			

<b>EXAMINER</b> <i>Yellen Hahn</i>	<b>DATE CONSIDERED</b> <i>considered on</i> <i>09/14/97, 900 11/15/02</i>
---------------------------------------	--

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 US Department of Commerce Patent and Trademark Office	ATTY DOCKET NO.:	SERIAL NO.:
	DDI-0028-CON1	Unassigned
	APPLICANT: Galen et al.	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	FILING DATE: Herewith	GROUP ART UNIT: Not assigned

✓	5384239	1/24/95	Saunders			
	5470752	11/28/95	Burd et al.			

## FOREIGN PATENT DOCUMENTS

EXAM. INITIALS	DOCUMENT NUMBER	DATE	COUNTRY	NAME	CLASS	SUB- CLASS	TRANSLATION (YES/NO)
✓	0473189A2	3/4/92	European	Sakamoto			
	0388782	9/26/90	European	Chen			

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages)

✓	Arnbruster, "Diabetes mellitus, protein glycation, and laboratory assays for monitoring long-term glycemic control." <u>Clinical Laboratory Science</u> , 3(3):184-188 (1990).
	Arnbruster, "Fructosamine: Structure, Analysis, and Clinical Usefulness." <u>Clinical Chemistry</u> , 33(12):2153-2163 (1987).
	Baker et al., "Clinical usefulness of estimation of serum fructosamine concentration as a screening test for diabetes mellitus." <u>British Med. J.</u> , 287:863-867 (1983).
	Benjamin and Sacks, "Glycated protein update: implications of recent studies, including the diabetes control and complications trial." <u>Clin. Chem.</u> , 40(5):683-687 (1994).
✓	Caines et al., "Colorimetric determination of non-enzymatically glycated albumin." <u>Clinical Biochemistry</u> , 19:26-30 (February 1986).

EXAMINER	Yellev Gal	DATE CONSIDERED	considered re 09/477,900 11/15/02
----------	------------	-----------------	--------------------------------------

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 US Department of Commerce Patent and Trademark Office  INFORMATION DISCLOSURE STATEMENT BY APPLICANT	ATTY DOCKET NO.: DDI-0028-CON1	SERIAL NO.: Unassigned
	APPLICANT: Galen et al.	
	FILING DATE: Herewith	GROUP ART UNIT: Not assigned

46		Candiloros, "Decreased Erythrocyte Membrane Fluidity in Poorly Controlled IDDM." <u>Diabetes Care</u> , 18(4):549-551 (1995).
		Cefalu et al., "Serum fructosamine as a screening test for diabetes in the elderly: a pilot study." <u>JAGS</u> , 41:1090-1094 (1993).
		Dix et al., "Glycohemoglobin and glucose tolerance tests compared as indicators of borderline diabetes." <u>Clin. Chem.</u> , 25(6):877-879 (1979).
		Dods and Bolmey, "Glycosylated hemoglobin assay and oral glucose tolerance test compared for detection of diabetes mellitus." <u>Clin. Chem.</u> , 25(5):764-768 (1979).
		Goldstein et al., "Is glycohemoglobin testing useful in diabetes mellitus? Lessons from the diabetes control and complications trial." <u>Clin. Chem.</u> , 40(8):1637-1640 (1994).
		Goldstein and Little, "The impact of the diabetes control and complications trial on the clinical laboratory." <u>Viewpoints</u> , 4 (1993).
		Guillausseau et al., "Comparison of HbA <sub>1c</sub> and fructosamine in diagnosis of glucose-tolerance abnormalities." <u>Diabetes Care</u> 13(8):898-890 (1990).
		Johnson et al., "Fructosamine: a new approach to the estimation of serum glycosylprotein. An index of diabetic control." <u>Clinica Chimica Acta</u> , 127:87-95 (1982).
		Kahn, "Tight blood glucose control shown beneficial for diabetes." <u>Clin. Chem. News</u> , 19(9) (1993).
		Larsen et al., "Effect of long-term monitoring of glycosylated hemoglobin levels in insulin-dependent diabetes mellitus." <u>New England J. of Med.</u> , 323(15):1021-1025 (1990).
		Pamphlet Insert to the Abbott Vision System, (1993)
✓		Pamphlet Insert to the Lifescan, ONE TOUCH II Blood Glucose Meter, (1990)

EXAMINER <i>Yelue Hale</i>	DATE CONSIDERED <i>considered</i> <i>09/477,900 11/15/02</i>
-------------------------------	---

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<b>FORM PTO-1449 US Department of Commerce Patent and Trademark Office</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>	<b>ATTY DOCKET NO.:</b> DDI-0028-CON1	<b>SERIAL NO.:</b> Unassigned
	<b>APPLICANT:</b> Galen et al.	
	<b>FILING DATE:</b> Herewith	<b>GROUP ART UNIT:</b> Not assigned

Y6		Rosen, "Protein-Bound glucose as a screening test for diabetes." <u>Hospital Practice</u> , 27:59-61 (1992).
		Rowe DJF, "The Measurement and Clinical Significance of Glycated Proteins." <u>Practical Diabetes</u> , 6(6) 256-260 (1989)
		Shima et al., "The relative value of glycated albumin, hemoglobin A <sub>1c</sub> and fructosamine when screening for diabetes mellitus." <u>Diabetes Research and Clin. Practice</u> , 7:243-250 (1989).
		Searcy and Bolland, "Fructosamine: The next step in diabetic management." <u>Amer. Clin. Lab.</u> 12(8) 1993.
		Thbsalemans et al., "The value of HbA <sub>1c</sub> and fructosamine in predicting impaired glucose tolerance - an alternative to OGTT to detect diabetes mellitus or gestational diabetes." <u>Ann. Clin. Biochem.</u> , 24:447-452 (1987).

<b>EXAMINER</b> <i>Yelver Gal</i>	<b>DATE CONSIDERED</b> <i>in the parent</i> <i>09/477,900 4/15/02</i>
-----------------------------------	--

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.